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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/241,455 | 02/02/1999 | NIKOLAI M. KRIVITSKI | | 8764 |

23387 7590 08/07/2003

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EXAMINER

SZMAL, BRIAN SCOTT

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3736

DATE MAILED: 08/07/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/241,455

Applicant(s)

KRIVITSKI, NIKOLAI M.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6,9-19 and 22-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6,9-16,18,19 and 22-43 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s): _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 102 & 35 USC § 103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Alt ('234).

Alt discloses a thermodilution catheter and method of determining cardiac output and further discloses an elongate catheter body having an inflation lumen and an injector lumen including a lateral port located along a side of the catheter body; an inflatable stenosis reducing balloon fluidly connected to the inflation lumen; and a dilution sensor fixedly connected to the catheter body at a location spaced from the exit port. See Column 5, lines 65-68; Column 6, lines 1-12 and 53-68; Column 7, lines 33-40; and Column 8, lines 8-32 and 49-55.

4. Claims 2-5, 9-13, 15, 16 and 18-42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Alt ('234). Alt, as discussed above, discloses a thermodilution catheter with a dilatation balloon and further disclose the blood property port is a fixed distance from the balloon; a

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sensor for measuring the flow rate; the sensor is located with respect to the vessel to minimize wall effects; a controller connected to the sensor to calculate the flow rate corresponding to the signal from the sensor; the port includes an aperture for introducing a blood property variant; the port and the sensor are spaced apart; a dilution indicator source; inserting the catheter into a vessel; measuring the flow rate of the vessel; reducing the stenosis in the vessel; measuring the flow rate a second time; the stenosis reducing procedure includes angioplasty; locating a plurality of sensors in the vessel; the sensor detects changes in electrical resistance; the sensor detects a thermal property of the blood; and the volume of indicator is injected as a bolus. See Column 5, lines 65-68; Column 6, lines 1-12 and 53-68; Column 7, lines 33-40; and Column 8, lines 8-32 and 49-55.

Even though Alt does not disclose the formula for measuring the blood flow past the sensor, Alt does disclose the use of a computer for calculating the flow rate. Since Alt discloses the use of a sensor and a computer for calculating the flow rate, it would have been obvious to one of ordinary skill in the art to have the computer use multiple flow rate formulas, including the claimed formula, to calculate the flow rate past the sensor. It also would have been obvious to rotate the sensor with respect to the vessel wall to reduce wall effects, since it is well known in the art that angioplasty catheters are capable of being rotated in vivo to navigate the vasculature.

5. Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt ('234) as applied to claims 9 and 34 above, and further in view of Quinn et al ('654).

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Alt, as discussed above, discloses a thermodilution catheter with a dilatation balloon, but fails to disclose the blood property change port including one of a heat sink and a heat source for creating a local temperature gradient.

Quinn et al discloses a multi-lumen, multi-parameter catheter and further discloses the blood property change port including one of a heat sink and a heat source for creating a local temperature gradient. See Column 5, lines 38-49.

Since both Alt and Quinn et al disclose the use of thermodilution catheters, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Alt to include the use of a heat source, as per the teachings of Quinn et al, since it is well known in the art that a heat source is an alternative means for creating a temperature gradient in the blood stream.

Allowable Subject Matter

6. Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

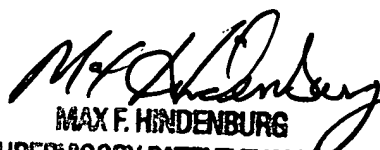
7. Applicant's arguments, see Paper No. 25, filed June 9, 2003, with respect to the rejection(s) of claim(s) 2-5, 9-19 and 22-43 under Quinn et al have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Alt ('234).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.



BS
August 4, 2003



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